KOELIS

K131948

510(k) SUMMARY

510(k) Summary for UROSTATION – 3D PROSTATE SUITE

MRI/3DTRUS FUSION OPTION

SECOND LOOK 3DTRUS FUSION OPTION

The 510(k) summary is submitted in accordance with the requirements of 21 CFR 807.92.

510(k) Owner:	KOELIS 5, avenue du Grand Sablon 38700 La Tronche FRANCE Phone: +33 476 637 588 Fax: +33 476 549.561
Contact Name:	Ms Laetitia GERVAIS Quality Manager Mail: gervais@koelis.com JUL 26 2013
Date Prepared:	04/30/2013

Proposed Device:

Trade Name:	UROSTATION - 3D PROSTATE SUITE
Common Name:	Medical Image Processing Software System
Classification Name:	System, Image processing, Radiological Picture archiving and communication system, 21 CFR PART 892.2050
Device Class	II
Product Code	LLZ

Cleared Device:

The Urostation system is substantially equivalent to:

510(k) Number	Device Name:
K100793	UROSTATION-3D Prostate Suite

Intended Use:

UROSTATION - 3D PROSTATE SUITE with MRI/3DTRUS fusion option and with Second Look 3DTRUS fusion option is a computer-based software application intended to process, visualize and record 3D digital ultrasound images of the prostate.

Indications for Use:

UROSTATION - 3D PROSTATE SUITE with MRI/3DTRUS fusion option and with Second Look 3DTRUS fusion option is intended to be used by physicians in the clinic or hospital for 2D and 3D visualization of the prostate gland and for the 3D transrectal ultrasound based fusion of multiple imaging modalities (ultrasound, MRI) in order to map such prostate gland. Additional software features include patient data management, multimodal data communication, multi-planar reconstruction, surface and volume rendering, organ delineation, region of interest delineation, 3D image registration and data reporting.

Device Description:

UROSTATION - 3D PROSTATE SUITE is a computer-based software application designed to process, visualize and record 3D digital ultrasound images of the prostate, and to manage patient and clinical data in the context of transrectal prostate biopsy. Software options provide the fusion of 3DTRUS with MRI or with other 3DTRUS modalities.

Hardware Platform and Operating System

The application runs on a standard Personal Computer under Microsoft Windows® operating system (version 7 or higher).

Peripheral and accessories

The application is controlled by a footswitch and manual input devices (mouse, keyboard),

It is designed to work in connection with commercially available 3D ultrasound scanners with Ethernet connection, 3D transrectal ultrasound probe and needle guide.

Software Features

UROSTATION - 3D PROSTATE SUITE implements image fusion and display algorithms to provide 3D representation of prostate biopsies.

A typical workflow enables the physician to intraoperatively visualize the 3D mapping of biopsies with respect to a 3DTRUS reference image of the patient's prostate.
For that purpose, 3D digital images may be transferred at any time from the 3D ultrasound scanner to the Urostation for registration and display, while the physician keeps track of the organ on the ultrasound scanner using the usual 2D live B mode.
Optionally, MRI/3DTRUS fusion allows the elastic registration of the 3DTRUS reference image with other imaging modalities (MRI here) in order to display the 3D biopsy mapping on multiple imaging modalities.
Optionally, Second Look 3DTRUS Fusion allows the elastic registration of the 3DTRUS reference image with a previously acquired 3DTRUS reference image of the same patient in order to superimpose two 3D biopsy mappings on a unique 3DTRUS reference image.
Alternatively, UROSTATION - 3D PROSTATE SUITE also provides a review mode that allows the mapping of histologic results on the said 3D reference image of the patient's prostate. Patient

information, images and 3D biopsy mapping may be stored or printed for future retrieval and examination.

Technological Characteristics compared with the cleared device:

UROSTATION - 3D PROSTATE SUITE with MRI/3DTRUS Fusion option and Second Look 3DTRUS Fusion option utilizes the same technological characteristics as the cleared device:

- Both are PC-based software applications that provide 2D/3D medical image acquisition and visualization for enhanced observation and analysis of the prostate gland.
- Both software architectures follow a workflow adapted to the physician's practice.
- Both systems implement a dedicated algorithm to visualize biopsies with respect to a single 3DTRUS reference image of the prostate.
- Both systems have no measurement features.
- Both systems provide in addition patient and clinical data management features.
- Both systems deal with 3D ultrasound images received from commercially available imaging devices.
- Both systems provide 3D image registration and data reporting features

UROSTATION - 3D PROSTATE SUITE with MRI/3DTRUS Fusion option and Second Look 3DTRUS Fusion option provide also additional features. These features are based on the same fundamental scientific technology and do not raise any safety or effectiveness concern in comparison with the cleared device:

- The MR/3DTRUS Fusion option implements the same principles of 3D model-based iterative matching of prostate data as the cleared device. More specifically, the implemented algorithm to fuse multimodal images (Ultrasound, MRI) is based on user-delineated 3D prostate contours. The accuracy and repeatability are equivalent.
- The Second Look 3DTRUS Fusion option implements the same principles and image-based matching of prostate data as the cleared device. The accuracy and repeatability are equivalent.
- The system provides patient data management, multimodal data communication, multi-planar reconstruction, surface and volume rendering, organ delineation, region of interest delineation, 3D image registration and data reporting

Substantial Equivalence Comparison Chart

<table>
<tr><td>Company:</td><td>KOELIS</td><td>KOELIS</td><td>KOELIS</td></tr>
<tr><td>System:</td><td>3D PROSTATE SUITE
3DTRUS prostate mapping</td><td>3D PROSTATE SUITE
MRI/3DTRUS FUSION OPTION</td><td>3D PROSTATE SUITE
SECOND LOOK 3DTRUS FUSION OPTION</td></tr>
<tr><td>510(k) number:</td><td>K100793</td><td colspan="2"></td></tr>
<tr><td rowspan="2">Function</td><td colspan="3">- 2D/3D image:
o acquisition
o viewing/reviewing
o processing
o registration
o storage
- Multi-Planar Reformatting (MPR)
- Volume rendering
- Patient and clinical data management
- Patient and clinical data reporting
- Printing</td></tr>
<tr><td>-</td><td>- Surface rendering
- Organ delineation
- Region of interest delineation</td><td>-</td></tr>
<tr><td>Intended Use:</td><td colspan="3">To process, visualize and record 3D digital ultrasound images of the prostate</td></tr>
<tr><td rowspan="2">Data Source:</td><td colspan="3">3D TRUS scanners</td></tr>
<tr><td>▪ 3D TRUS scanners</td><td>- 3D TRUS scanners
- Dicom MR images</td><td>▪ 3D TRUS scanners</td></tr>
<tr><td>Physical Characterization:</td><td colspan="3">Software package
- operates on standard PC-based hardware
- Windows operating system</td></tr>
</table>

Conclusion:

The results of comparing the intended uses, functions and technological characteristics of the UROSTATION - 3D PROSTATE SUITE including MRI/3DTRUS Fusion option and Second Look 3DTRUS Fusion option with its cleared device shows that the system is as safe and as effective as its cleared device.

UROSTATION - 3D PROSTATE SUITE with MRI/3DTRUS fusion option and Second Look 3DTRUS fusion option is substantially equivalent to existing product currently on the market.

Performance summary

UROSTATION - 3D PROSTATE SUITE'S 3D display and image fusion capabilities are based on a patented technology called Organ-Based Tracking. The ability of Urostation to register biopsy cores, and optionally MR lesions, on a reference 3DTRUS image of the prostate would consequently allow to assist the physician in targeting different regions of the prostate.

The performance and accuracy of KOELIS fusion technology has been validated on phantom and patient data, as shown in the following studies.

Elastic MR/3DTRUS image fusion:
[Brolis et al, Internal Technical Review, 2012]

From 17 contoured TRUS patient volumes, 850 simulated deformations were registered using Koelis elastic registration method. The overall time for registration was 3.9s. After elastic registration the mean distance between the reference and deformed prostates was 0.09mm The RMS error stemming from deformations in the probe area is reduced from 4.1mm down to 1.9mm. Clinical validation has been performed on 49 patients in 5 clinical sites. A total of 112 landmark pairs were identified and approved by physicians. The registration quality is measured using the distance between contours and between landmarks. Surfaces were superimposed after elastic registration with 0.7±0.3mm mean accuracy. The mean distance between corresponding landmarks was 1.7±0.7 mm after elastic registration, and the RMS error was 1.9mm.

Elastic 3DTRUS/3DTRUS image fusion and organ tracking:
[Baumann et al, Medical Image Analysis 16 (2012) 562–576]

A volume-swept 3DTRUS based tracking system for fast and accurate estimation of prostate tissue motion is proposed. Prostate deformations are estimated with elastic registration to maximize accuracy. The system is robust with only 17 registration failures out of 786 (2%) biopsy volumes acquired from 47 patients during biopsy sessions. Accuracy was evaluated to 0.76mm±0.52mm using fiducials on 687 registered volumes stemming from 40 patients.

Targeting Accuracy of Urostation
[Ukimura et al, J. Urol. Vol. 187, 1080-1086, 2012]

The accuracy of the Urostation 3DTRUS system for image-based mapping biopsies was evaluated in 6 prostate phantoms, 3 containing 3 hypoechoic lesions and 3 containing 3 isoechoic but MRI-visible lesions, to perform MR fusion guided biopsy. Three targeted biopsies were done per lesion. A total of 27 ultrasound guided biopsies were targeted into 9 hypoechoic lesions. All 27 biopsies (100%) successfully hit the target lesion with a procedural targeting error of 1.52±0.78mm and a system registration error of 0.83mm, resulting in an overall error of 2.35mm. Of the 27 MR fusion biopsies 24 (84%) hit the lesion. For isoechoic lesions mean procedural targeting error was 2.09±1.28mm, resulting in an overall error of 2.92mm.

Conclusion on performance and accuracy:

The overall fusion RMS error of the UROSTATION - 3D PROSTATE SUITE, combines preoperative MRI/3DTRUS fusion (1.9mm error) and intraoperative 3DTRUS/3DTRUS fusion used for organ tracking (0.76mm error). The total RMS error of the visualization process is hence 2.05mm at any time during the procedure, giving the physician a probability greater than 95% to hit the lesion according to *[Karnick et al, Med. Phys. 37 (2), 802–813]*.

KOELIS therefore concluded that the accuracy provided by the UROSTATION fusion technology is clinically acceptable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 26, 2013

LAETITIA GERVAIS
QUALITY MANAGER
KOELIS
5, AVENUE DU GRAND SABLON
LA TRONCHE 38700
FRANCE

Re: K131448
Trade/Device Name: Urostation - 3D Prostate Suite, MRI/3DTRUS Fusion Option, Second Look 3DTRUS Fusion Option
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 20, 2013
Received: June 03, 2013

Dear Ms. Gervais:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131448

Device Name: **UROSTATION 3D PROSTATE SUITE**

MRI/3DTRUS FUSION OPTION

SECOND LOOK 3DTRUS FUSION OPTION

Indications for Use:

UROSTATION - 3D PROSTATE SUITE with MRI/3DTRUS fusion option and with Second Look 3DTRUS fusion option is intended to be used by physicians in the clinic or hospital for 2D and 3D visualization of the prostate gland and for the 3D transrectal ultrasound based fusion of multiple imaging modalities (ultrasound, MRI) in order to map such prostate gland. Additional software features include patient data management, multimodal data communication, multi-planar reconstruction, surface and volume rendering, organ delineation, region of interest delineation, 3D image registration and data reporting.

Prescription Use _X_____ ~~AND/OR~~ Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K131448